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STRENGTHENING PHARMACOVIGILANCE SYSTEMS IN SWAZILAND TO IMPROVE PATIENT SAFETY AND TREATMENT OUTCOMES



CHALLENGE Implementing comprehensive pharmacovigilance programs in resource-limited settings

Along with passive surveillance, sentinel site-based active surveillance is a key approach to strengthening a country's pharmacovigilance (PV) and medicine safety system. As new essential medicines for HIV/AIDS and drug-resistant tuberculosis (TB) are being introduced and scaled up in resource-limited countries, monitoring adverse drug reactions (ADRs) and therapeutic effectiveness associated with these medicines is increasingly important. A well-integrated, comprehensive pharmacovigilance system is necessary for improving patient management, making evidence-based treatment decisions, and promoting rational medicine use.

Swaziland has a high burden of both HIV/AIDS and TB, and the nation's pharmacovigilance system has traditionally relied on passive surveillance mechanisms based on spontaneous

reporting. In a passive surveillance system, health professionals and others are encouraged to report adverse events, but no other active measures are used. Thus, relying on passive surveillance alone can lead to under-detection and underreporting of adverse drug events. In Swaziland, the Ministry of Health (MOH) had only been receiving about 30 adverse reaction reports per year since the passive surveillance system was implemented in 2010. This low level of reporting spurred the introduction of an active surveillance system to complement the passive system.

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SIAPS ACTIVITIES Introducing active surveillance measures for HIV/AIDS and TB treatment programs

SIAPS mobilized stakeholders from the Swaziland National AIDS Program (SNAP) and the National Tuberculosis Control Program (NTCP) to introduce and implement the Sentinel Site-based Active Surveillance System for Antiretroviral and Anti-TB (SSASSA) treatment programs. SIAPS partnered with the Pharmacovigilance Unit of the MOH to create the protocol and tools for the electronic

SSASSA system, and developed a patient recruitment system at HIV and TB sites.

The new system documents and quantifies incidence rates of adverse events associated with antiretrovirals (ARVs) and anti-TB medicines and determines risk factors at selected sentinel sites. In addition to collecting and compiling the type

The SSASSA was officially launched in 2013, and subsequently installed at five hospitals and one clinic.

RESULTS

Data from active surveillance help monitor medicines safety and enable data-driven decision making

support the MOH in developing *Medicine Safety Watch*, a quarterly newsletter designed to disseminate information on medicines safety. Copies are printed and distributed to all health facilities, and electronic copies are mailed to stakeholders.

Symptom	Patient Count
Chest Pain	1
Hepatitis	3
Kidney failure	5
Muscle pain	1
Nausea	3
Peripheral neuropathy	15
Rash	11
Vomiting	4
Allergic reaction	1
Diarrhea	4
Dizziness	7
Neutrophilia	1
Painful lower leg 3/52	1
Swallowing	1

Follow-up Visit Outcome	Patient Count
Follow-up visit early or on time & forgot to use medicine	9
Follow-up visit early or on time & remembered to use medicine	385
Late follow-up visit & forgot to use medicine	13
Late follow-up visit & remembered to use medicine	20
Transferred Out	1

One of the main challenges of this activity is that only four of the six sites have enrolled patients and captured data using the active surveillance system. The MOH, with support from SIAPS, is exploring the underlying constraints to using the system at these sites. In addition, data collection has not been optimal at all facilities. Recommendations have been made to modify SSASSA data fields to improve the collection of reliable data, and to update the SSASSA and the Data Collection and Analysis Tool to address compatibility issues.

The use of SSASSA in Swaziland demonstrates that active surveillance programs, which have mostly been implemented almost exclusively in industrialized countries, can be initiated successfully in resource-limited settings if system-based support and local collaboration are in place. Such an active surveillance system creates an enabling environment for regulatory decision-making and risk management planning. National bodies have provided overall leadership and governance for the implementation of these activities, and have identified and engaged other key stakeholders to contribute. Human resource capacity has also been strengthened, as evidenced by the extensive training that health care workers have received on capturing data and reporting ADRs.

NEXT STEPS

Scaling up active surveillance to monitor other medicines in additional settings

The SSASSA active surveillance system will be scaled up to monitor the safety of ARV and TB regimens throughout the country. It will also be applied to future active surveillance of other medicines, settings, and populations to prevent harmful health outcomes.

SIAPS is also currently providing support in Namibia to implement active surveillance pharmacovigilance at two sentinel HIV/AIDS sites. Drawing on lessons learned from these two countries, SIAPS plans to help implement active surveillance programs in other countries.

Development of Sustainable HIV/TB Active Surveillance System in Swaziland – Protocol and Operational Plan

Garb M. and Joshi M. 2012. Technical Assistance for the Development of Instructor's Guides for Implementing Pre-service and In-service Curricula on Pharmacovigilance in Vietnam.

ABOUT SIAPS | The Systems for Improved Access to Pharmaceuticals and Services (SIAPS) program works to assure access to quality pharmaceutical products and effective pharmaceutical services through systems-strengthening approaches to achieve positive and lasting health outcomes. SIAPS is funded by the US Agency for International Development (USAID) and is implemented by Management Sciences for Health. For more information, visit www.SIAPSprogram.org.



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